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IN THE

Supreme Court of the United States

DONNA S. RIEGEL, individually and
as administrator of the estate of Charles R. Riegel,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

Throughout their briefs, Medtronic and its amici speak as if the traditional state-law civil justice system did not exist. They talk about what "would" happen if damages claims "could" proceed against manufacturers of medical devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA"). This purported concern need not worry us here because damages claims against manufacturers of PMA devices are not new remedies that the Court is being asked to create. Damages claims pre-existed the Medical Device Amendments of 1976 ("MDA") and have co-existed with PMA for 30 years since then. Medtronic and its amici offer no evidence that manufacturers have had difficulty complying with federal device requirements while also being held accountable to patients under state law for injuries caused by their products.[1]

In essence, Medtronic's argument consists of the mantra that PMA transforms a manufacturer's device design and labeling into federal requirements. That argument misconceives the nature of PMA, which allows a manufacturer to sell a particular device but does not impose federal design and labeling specifications. Thus, no federal design or labeling specifications exist for the type of catheter at issue here. The PMA permitted Medtronic to market a balloon catheter with the

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[1]Although many tort cases settle without a court decision, the number of reported cases involving PMA devices is nonetheless significant. *See, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999); *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995); *In re Guidant Corp. Implantable Defibs. Prods. Liab. Litig.*, MDL No. 05-1708, 2007 WL 2071804 (D. Minn. July 16, 2007); *Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992); *Donnely v. Copeland Intra Lenses, Inc.*, 87 F.R.D. 80 (E.D.N.Y. 1980); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E. 2d 1149 (Ill. 2000); *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997); *Kernats v. Smith Indus. Med. Sys., Inc.*, 669 N.E. 2d 1300 (Ill. App. 1996).

particular design and label that injured Mr. Riegel, but Medtronic was not required to choose those specifications. If Medtronic chooses to market a balloon catheter, it can select any of the several designs and labels for which it has obtained approval, or, if it is unsatisfied with those, obtain approval for new ones.

Medtronic's argument also ignores important elements of the federal regulatory scheme, such as the regulations allowing manufacturers to alter labeling to enhance patient safety. In addition, the federal labeling requirements applicable to Medtronic's PMA device were substantially the same as those at issue in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The Court has already held that those requirements do not reflect "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

Finally, to prevail here, Medtronic must show not only a device-specific federal requirement, but also a counterpart state requirement. Medtronic's brief fails to distinguish—indeed it makes little effort to distinguish—the state-law duties here from those found too general to warrant preemption in *Lohr*.

I. PMA Does Not Establish Device-Specific Requirements That Are Counterparts To Any State-Law Duties Enforced Through Damages Claims.

The parties agree that the PMA process can be demanding and time-consuming. However, when the process is complete and the FDA grants PMA, the requirements imposed on the manufacturer generally are neither "specific" to the device nor counterparts to any "different" or "additional" state requirement relevant here, as required for preemption under 21 U.S.C. § 360k(a). *See Lohr*, 518 U.S. at 200-01.

A. Medtronic's response to this point is twofold. First, the company emphasizes the rigor of PMA review. Medtronic never explains, however, how the number of hours that the

FDA spends making a PMA determination relates to the question of preemptive requirements under § 360k(a). The PMA route to marketing differs from the 510(k) route. But the relevant question is not what steps a manufacturer must take to get a product to market. The question is what requirements are imposed as a result of taking those steps and, as to each such requirement, whether it is "'specific' to a 'particular device'" or has a "specific counter-part" in state law. *Lohr*, 518 U.S. at 500 (quoting 21 C.F.R. § 808.1(d)). The rigor of the PMA review process does not answer these questions. *See Webster v. Pacesetter, Inc.*, 171 F. Supp. 2d 1, 11 (D.D.C. 2001) ("[I]t is the specificity of the regulatory mandate, not the length and cost of review, that is relevant under Section 360k."); *Sowell v. Bausch & Lomb, Inc.*, 230 A.D.2d 77, 84 (N.Y. App. Div. 1997) ("[W]hile a PMA review is considerably more rigorous and detailed than the premarket notification at issue in [*Lohr*], it is, in fact, no more 'specific' a requirement.").

Next, Medtronic argues that when the FDA grants PMA, it imposes a number of requirements on the design and labeling of the device. Thus, Medtronic states (at 17) that "the manufacturer may market the device *only* as specified in the PMA application." Yet at the same time, Medtronic acknowledges that a manufacturer may alter the design or labeling, with FDA approval. *See also* 21 C.F.R. § 814.39(d) (listing labeling changes that may be made without pre-approval). Thus, a manufacturer can market a particular device or type of device using any number of designs and labels, at its own choosing.

Recent cases involving injuries caused by another PMA device offer a real-world illustration of this point. In December 2002, the FDA granted PMA to a Medtronic implantable defibrillator. In January 2003, Medtronic identified a design defect that could cause the battery to fail. Medtronic then sought and obtained approval for three additional models that used the same battery, never advising the FDA of the serious problem. *In re Medtronic Implantable Defibs.* (MDL), 465 F. Supp. 2d 886, 889 (D. Minn. 2006). In October 2003,

Medtronic filed a PMA supplement seeking approval for design changes to improve the defective battery used in the various defibrillators, and the FDA granted the supplemental PMA later that month. Medtronic then sold the devices with both the old, defective design and the new, improved design. *Blunt v. Medtronic, Inc.*, 2007 WL 2176136, ¶¶ 2-3 (Wis. App. 2007). Although Medtronic knew that the older model had a design flaw, it wanted to use up its inventory. *Id.* ¶ 22 (Fine, J., dissenting).

The facts surrounding this device differ from the facts presented here, but Medtronic's theory would require the same outcome in each case. In lawsuits seeking damages for injuries caused by the defective defibrillators, including those implanted *after* the safer model had been approved, Medtronic has argued that PMA of the original design constituted a "specific federal requirement" for purposes of § 360k(a), *see Blunt*, 2007 WL 2176136, ¶ 13, even though the company had already redesigned the product to correct a dangerous defect and was already marketing the redesign. And if it were true that PMA constituted a specific design and labeling requirement for purposes of § 360k(a), then the PMA's preemptive effect would continue even after the company had redesigned the product, as long as the FDA had not withdrawn PMA (an unusual occurrence). Yet if the company were subject to a "specific federal requirement" that its defibrillator have the original design, how could it also be subject to a "specific federal requirement" that the defibrillator have the revised design? The answer is that it cannot. The company is permitted to sell products with either design because PMA is a marketing license, *allowing* a company to market a product with a particular design, but not *requiring* it to market the product with that design as opposed to any other approved (or approvable) design. The requirement is that the manufacturer obtain permission to market its product, not that it design the product in any particular way. Thus, Medtronic marketed the catheter at issue in this case first with one design and later with

others, as it twice submitted PMA supplements concerning design changes. JA 16, 26.

Moreover, Medtronic does not even mention 21 C.F.R. § 814.39(d). Under that regulation, manufacturers of PMA devices may strengthen a contraindication, precaution, or warning; strengthen an instruction intended to enhance the safe use of the device; and delete misleading or false statements from the label, *without* prior FDA approval. *Id.* § 814.39(d)(2).

The United States recognizes that § 814.39(d) belies the argument that PMA establishes preemptive labeling requirements. It suggests, first, that the sorts of changes allowed under this regulation "do not appear to apply here." US Br. 13-14. That suggestion is incorrect because Ms. Riegel's failure-to-warn claim is based on the inadequacy of the warnings, precautions, and instructions. *See* Pet. Br. 11, 42-43. The United States then notes that, pursuant to a draft guidance document issued earlier this year, changes under § 814.39(d) must be based on "newly-acquired safety-related information" "not previously considered by the FDA." US Br. 14 (quoting www.fda.gov/cdrh/ode/guidance/1584.pdf ("March 2007 Guidance")). Even if the guidance were binding, *but see* March 2007 Guidance at 1 (guidance "does not operate to bind FDA or the public"), and even if it applied to a defect identified in the 1990s in a device no longer on the market, the guidance would have permitted Medtronic to make changes based on "newly-acquired" information derived from post-approval adverse event reports. In any event, although some labeling changes require FDA pre-approval, a manufacturer that never sought to make and was never denied permission to make a relevant change cannot rightly invoke the pre-approval requirement as a bar to state-law liability.

B. As the parties have explained, PMA represents the FDA's determination that a manufacturer has demonstrated that a device offers a "reasonable assurance of safety and effectiveness." The consequence of this determination is, "in effect, a private license granting the applicant (or owner) permission to

market the device." FDA, *Device Advice—Premarket Approval (PMA)*, www.fda.gov/cdrh/devadvice/pma/printer.html at 1 ("*Device Advice*"). Medtronic is correct that, as long as the manufacturer chooses to market that version of the device, it must comply with various conditions imposed by the license. However, the requirements imposed are no more specific than the requirements imposed on the 510(k) device at issue in *Lohr*. In fact, many are the same.

For example, whether marketing permission is obtained via the PMA process or the 510(k) process, the manufacturer cannot make design changes that affect the safety or effectiveness of the device without FDA's permission. *Compare* 21 C.F.R. § 814.39 (PMA supplements), *with id.* at § 807.81(a)(3)(i) (new 510(k) submissions). With respect to labeling, the federal requirements are almost identical. The regulation that governs the content of prescription device labeling, 21 C.F.R. § 801.109, applies to both PMA and 510(k) devices. And both PMA and 510(k) labels cannot be "false or misleading in any particular." 21 U.S.C. §§ 331(a), 352(a). Medtronic suggests (at 21) that the requirements imposed with respect to its catheter were more "specific" than those imposed on the pacemaker lead in *Lohr* because the catheter's label had to adhere to the approved labeling. However, proposed labeling must be included in the marketing application for both PMA and 510(k) devices. *See* 21 C.F.R. § 807.87(e) (510(k) submission requirements). And many post-marketing labeling changes for both PMA and 510(k) devices require approval, either in advance of making the change or after the fact. *See id.* § 814.39(d) (listing changes to PMA device labels that may be made without preapproval); *id.* § 807.81(a)(3)(ii) (labeling change requiring submission of new 510(k)); FDA, *Deciding When to Submit a 510(k) For a Change to an Existing Device* 9-12 (Jan. 1997), www.fda.gov/cdrh/ode/510kmod.html (listing changes to 510(k) device labels that require new 510(k) submissions).

Medtronic's argument is at heart that an FDA finding that a device presents reasonable assurance of safety and effectiveness should preempt a state-law damages remedy for design defect or inadequate labeling. That argument has no support in § 360k(a), which looks not to federal "findings" but to counterpart state and federal "requirements." The question is not what the FDA has found, but what the FDA has required.

C. Medtronic takes issue (at 19 n.3) with amicus AARP's characterization of PMA as a "one-time licensing scheme." The FDA itself, however, describes PMA as a "license." *Device Advice* at 1. In any event, Medtronic's response to the AARP shows that, although regulation continues after the FDA grants PMA, post-approval oversight is strikingly similar for PMA and 510(k) devices. Medtronic first states that manufacturers of PMA devices must inform the FDA of adverse events associated with approved devices, but that obligation applies to *all* manufacturers, regardless of the route that the device took to get to the market. *See* 21 C.F.R. § 803.50. Citing 21 U.S.C. § 360(h), Medtronic also notes that the FDA may undertake periodic inspections of PMA manufacturing facilities, but that regulation also applies to both PMA and 510(k) devices. *See also* 21 C.F.R. Part 820 (good manufacturing practices regulations applicable to all devices). And Medtronic cites the FDA's power under 21 U.S.C. § 360h to order a manufacturer to repair, replace, recall, or cease distribution of a device. Again, that provision applies to all devices, not only to PMA devices. In the end, the only requirement that Medtronic identifies that concerns PMA devices but not 510(k) devices is the submission of an annual report summarizing studies concerning the device. *See* 21 C.F.R. § 814.84(b). That requirement, however, does not relate to any aspect of device design or labeling and provides no basis for distinguishing this case from *Lohr*.

D. Medtronic states (at 22, 23) that Ms. Riegel has insisted that *only* FDA *regulations* can have preemptive effect under § 360k(a) and that PMA "does not have preemptive effect."

These characterizations of Ms. Riegel's argument are wrong. *See* Pet. Br. 25 ("The Riegels agree that PMA may have a preemptive effect."). Simply saying that PMA is preemptive, however, begs the question of what PMA preempts. *See also* Chamber of Commerce Br. 21 (arguing that Congress intended PMA to preempt but failing to consider *what* Congress intended it to preempt). Under § 360k(a), as construed in both *Lohr*, 518 U.S. at 500, and 21 C.F.R. § 808.1(d), preemption turns on counterpart state and federal requirements. Thus, once the FDA calls for PMA for a device, any state premarket approval requirement is preempted. But product liability claims for design defect or failure to warn are not counterpart requirements to PMA--they do not address the same topic (marketing approval)—and thus they are not preempted by PMA. Before 2003, the FDA understood § 360k(a) in just this way. *See, e.g.*, 45 Fed. Reg. 67321, 67323 (1980); 43 Fed. Reg. 18661, 18664 (1978); Br. of US as Amicus Curiae at 14-17, *Smith Indus. Med. Sys. v. Kernats*, 522 U.S. 1044 (1998) (No. 96-1407) ("U.S. *Kernats* Br."). This understanding of § 360k(a)—that it requires subject matter overlap between the federal and state laws—is also reflected in Justice Breyer's concurrence in *Lohr*, which posited that an FDA regulation that required 2-inch hearing aid wires would preempt a state regulation requiring 1-inch wires, but would not preempt state hearing aid rules addressing other aspects of the device, such as rules relating to packaging. 518 U.S. at 504, 505.

Accordingly, Medtronic's argument (at 21 n.4) that it cannot be held liable for failing to warn through a "Dear Doctor" letter because federal law allows but does not require manufacturers to send Dear Doctor letters must fail. Because federal law does not impose requirements with regard to Dear Doctor letters, a failure-to-warn claim based on the company's failure to send a letter clarifying the instructions for use or strengthening the warnings has no federal counterpart. It thus is not preempted by § 360k(a). *See Lohr*, 518 U.S. at 494 (where no design requirement in effect, § 360k(a) does not preempt design claim); 21 C.F.R. § 808.1(d) (state requirements

preempted "when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to the device under the act"); 43 Fed. Reg. 18663 (state device laws not preempted until such time as FDA implements counterpart federal requirements).

Medtronic (at 23-24) likewise takes issue with the distinction between PMAs granted on the condition that the product comply with device-specific requirements issued under 21 C.F.R. § 814.44(e), and PMAs granted without such specific conditions. *See* US Br. 15 (making same argument). Medtronic professes to find the distinction unsupportable, yet it flows directly from § 360k(a) and the FDA's implementing regulations, which premise preemption on device-specific requirements. *Cf. Puerto Rico Dep't of Consumer Affairs v. ISLA Petroleum Corp.*, 485 U.S. 495, 503 (1988) ("There is no federal pre-emption *in vacuo*, without a congressional text or a federal statute to assert it.") Although § 814.44(e) gives the FDA some authority to impose specific design and labeling requirements through the PMA process, the authority to impose requirements is not equivalent to the exercise of that authority. *See Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (decision not to issue regulation requiring design feature does not pre-empt damages claims based on injury caused by failure to install that feature); *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995) (same); *cf. Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant pre-emption of a state statute."). As the United States previously explained to the Court:

> If (as in this case) the FDA has not set out specific federal requirements for the particular device, the manufacturer may select any design, manufacturing, or labeling features that will satisfy the general minimum standards in the Act and regulations, and it may obtain . . . PMA on the basis of that selection if the FDA approves the application. Because the FDA has not imposed any specific substantive requirements on

> petitioner's design of the [device at issue] in the course of the review process, that design does not represent a specific federal requirement that preempts state common law requirements.

U.S. *Kernats* Br. 16. Review of current FDA regulations shows that, as the United States represented to the Court in 1997, the FDA "imposes such specific requirements on Class III devices only in extraordinary circumstances." *Id.* at 15. For these reasons, preemptive requirements applicable to Medtronic's catheter did not flow from the PMA itself.

E. In 1996 in *Lohr*, in 1997 in *Kernats*, and in 2000 in *Buckman v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001), the FDA filed briefs in this Court arguing for a narrow construction of § 360k(a) that reflected the approach of the FDA's regulation, 21 C.F.R. § 808.1(d). In the most recent of the three briefs, the agency described *Lohr*'s holding with approval and in a manner consistent with Ms. Riegel's reading, calling it a "sensible and administrable line" for determining the kind of federal requirements that "can have preemptive force" under § 360k(a). Br. of US as Amicus Curiae at 12, *Buckman v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001) (No. 98-1768). Citing regulations that establish specific labeling, testing, or performance standards for particular devices, the United States explained that these kinds of FDA requirements preempted different or additional "counterpart state requirements" because the "federal requirements are stated with specificity and apply to a specific device or set of devices." *Id.* In contrast, FDA's "labeling requirements do not have preemptive force" because they "are stated at a high level of generality and apply to all devices." *Id.*

The United States has now done an about-face with respect to the preemptive scope of PMA, as its brief in this case (at 24) concedes. Nonetheless, the United States asks for deference to its current view. Deference is unwarranted. In *Lohr*, the Court gave "substantial weight" to FDA regulations issued after notice-and-comment rulemaking, 518 U.S. at 496, not to the

United States's brief, and those regulations have not changed. Notably, the United States's amicus brief at the petition stage in this case, which primarily made a merits argument, did not even cite the preemption regulations. And its brief at the merits stage relies on them only sparingly. *See* US Br. 15, 27, 28.[2] For this reason, "[a]lthough generally 'an agency's construction of its own regulations is entitled to substantial deference,' *Lyng v. Payne*, 476 U.S. 926, 939 (1986), no such deference is appropriate," or even comes into play, with respect to the agency's view here because it exists apart from and in contradiction with the regulations. *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference due to government depends on, among other things, consistency and formality of government's position).

To the extent that the agency's view as expressed in 21 C.F.R. § 808.1(d) informed the Court's construction of § 360k(a) in *Lohr*, it should do so here as a matter of stare decisis. At the same time, in light of the agency's complete reversal on a question of statutory interpretation and the fact that the Court has before it a precedent construing that statute, the views expressed in the United States's latest amicus brief deserve no weight. *Cf. Bates v. Dow AgroSciences*, 544 U.S. 431, 449, 451-52 (2005) (giving no weight to agency's view of preemption in light of agency's reversal).

II. The State-Law Duties At Issue Here Are Indistinguishable From The Duties That *Lohr* Held Were Too General To Trigger Section 360k(a).

In *Lohr*, the Court held that the common-law duties at issue in that lawsuit did not trigger § 360k(a). The majority opinion explained that such "general" state requirements "are not the kinds of requirements that Congress and the FDA feared would

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[2]The United States's brief also cites § 808.1(d) as background (US Br. 4, 5, 9, 11) and for an uncontested point (*id.* at 20).

impede the ability of federal regulators to implement and enforce specific federal requirements." 518 U.S. at 501. For example, "the predicate for the failure to warn claim" alleged by the Lohrs was "the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Id.* The Court stated that "[t]hese general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of the work force." *Id.* at 501-02. The conclusion that the "generality" of the state-law duties at issue "leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices," *id.* at 502, is a holding of *Lohr*.

If merely enforcing a general state-law duty in a device case transformed that duty into a device-specific requirement, then *Lohr*'s discussion of this point would have been unnecessary. Medtronic, however, puts *Lohr*'s holding to the side and argues (at 35-36) that Ms. Riegel's claims are preempted under Justice Breyer's concurrence. First, under basic principles of stare decisis, a separate concurrence, regardless of its content, does not alter the meaning of a majority opinion of this Court. *Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001); *see Maryland v. Wilson*, 519 U.S. 408, 413 (1997) (concurring opinion does not establish precedent); *see also Agostini v. Felton*, 521 U.S. 203, 217 (1997) (state of the law not affected by views of five Justices in concurring opinions).

Second, Ms. Riegel's damages claims, based on general state-law duties with respect to the design and labeling of dangerous products, do not involve specific state-law requirements of the "2-inch wire" variety described in Justice Breyer's concurrence, any more than did the claims presented in *Lohr*. In fact, the entirety of Medtronic's argument on this point would be equally applicable to the state-law duties in *Lohr*, yet a majority of the Court, including the concurring Justice, rejected that theory. On the state-law side of the pre-

emption analysis, there is no difference between this case and *Lohr*.[3]

III. Ms. Riegel's State-Law Claims Are Based On Duties That Parallel Federal Requirements.

This Court has unanimously held that state-law requirements that parallel federal requirements do not fall within the preemptive scope of § 360k(a). *Lohr*, 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); *see also Bates*, 544 U.S. at 447-48 (citing *Lohr*). Ms. Riegel's claims are therefore not preempted to the extent that they are premised on state-law requirements that parallel requirements imposed under the MDA.

Medtronic first tries to avoid the point by asserting (at 40) that Ms. Riegel waived any argument based on *Lohr*'s unanimous identity-of-requirements holding by not making the argument below. However, *Lohr*'s holding cannot be so easily side-stepped. To begin with, Ms. Riegel's opening brief in the court of appeals did make this point. *See* Appellants' Br. 31 (arguing that warning claim parallels requirements of 21 C.F.R. § 814.39(d)). Moreover, although this Court generally will not consider *issues* neither raised nor decided below, *Travelers Cas. & Sur. Co. v. Pacific Gas & Elec. Co.*, 127 S. Ct. 1199, 1207 (2007), Ms. Riegel's argument on this point does not raise a new issue. Below, she argued both that federal requirements do not preempt her claims and that *Lohr* supports her argument. Highlighting a particular paragraph of *Lohr* is not raising a new "issue." *See also Nelson v. Adams USA, Inc.*, 529 U.S. 460, 469 (2000) (issue preservation "does not demand the incantation of particular words; rather, it requires that the lower court

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[3]Amicus Chamber of Commerce (at 11-12) argues at length that it would not make sense to hold that common-law claims are not preempted but that state statutes codifying the common law are preempted. Ms. Riegel has not drawn that distinction. Her point is that § 360k(a) does not preempt damages claims based on state-law duties of general applicability.

be fairly put on notice as to the substance of the issue"); *National Bank of Commerce of El Dorado v. Kimberly-Clark*, 38 F.3d 988, 992 n.2 (8th Cir. 1994) (where complaint alleges failure to warn, argument that defendant did not comply with FDA regulations is not a new argument, but a standard by which to measure defendant's conduct).[4]

Turning to the merits, Medtronic contends (at 41) that a design defect or inadequate labeling claim is "directly at odds" with federal requirements because, through PMA, the FDA "found [the device] to be safe and effective." PMA, however, is not a finding that a device *is* safe and effective, but that the application presents "reasonable assurance" of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C). The statute and regulations recognize that the FDA's finding that a device carries "reasonable assurance" of safety and effectiveness may be wrong, either initially or because of later advances in technology. *See* H.R. Rep. No. 94-853 at 23, 32 (1976) (discussing patient notification and PMA withdrawal provisions). For example, as noted above, FDA regulations set forth procedures for manufacturers to revise PMA design and labeling to enhance safety or effectiveness. 21 C.F.R. § 814.39. In addition, manufacturers must submit adverse event reports to the FDA, *id.* § 803.50 (applicable to all devices), and an annual report of clinical and nonclinical studies, *id.* 814.84(b), to allow the FDA continually to reassess the risk/benefit determination made through the PMA process. Further manifesting that PMA is not a federal finding that a product is not defective, the FDA may order a PMA device (or any device) recalled or repaired. 21 U.S.C. § 360h; 21 C.F.R. § 810.10.

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[4]In contrast, Washington Legal Foundation's argument that the MDA *impliedly* preempts damages claims presents an issue neither raised nor decided below. Moreover, implied preemption is not fairly encompassed in the question presented, which asks "[w]hether the *express preemption provision* of the [MDA], 21 U.S.C. § 360k(a), preempts state-law claims ." Pet. i (emphasis added).

And, of course, the manufacturer is free to recall or discontinue a defective device, without running afoul of the PMA determination. *See, e.g.*, B. Feder, *Patients Warned as Maker Halts Sale of Heart Implant Part*, N.Y. Times, Oct. 15, 2007 (describing recent Medtronic recall).

In light of the many statutory and regulatory provisions premised on and reiterating that a PMA device may prove to be defective, Medtronic's simplistic argument—essentially, that if the FDA granted PMA, then the product is safe—falls well short of demonstrating that the state-law duties at issue (*see* Pet. Br. 40-42) are not parallel to federal requirements. Moreover, Medtronic does not even attempt a response to Ms. Riegel's discussion of the parallel between the federal labeling requirements and the state-law inadequate labeling claim.

Taking a more realistic stance, the United States says (at 23 n.4) that an existing PMA "strongly suggests" that a device is not defective. This statement reflects that PMA is best considered as a defense on the merits, not as a "get-out-of-jail-free card" precluding consideration of the merits. The usual common-law rule is that compliance with a safety statute or regulation is relevant in a products liability case to "suggest" that the product is not defective, but does not preclude a finding of defect. *See* Restatement (Third) of Torts: Prods. Liab. § 4(b) & Reporters' Note, comment e (1988).

In sum, at the very least, under *Lohr* and *Bates*, Ms. Riegel is entitled to try her case under jury instructions that track applicable federal requirements.

IV. The Background, Structure, and Purpose of the MDA Demonstrate That Section 360k(a) Does Not Broadly Preempt Damages Claims.

A. Medtronic does not contest that, in enacting the MDA, Congress did not express a word of concern about damages claims. It does not contest that Congress's enactment of § 360k(a) was motivated by concern about California's medical device regulation, not concern about ongoing products liability

litigation against device manufacturers. And although the FDA designated certain devices as PMA devices very soon after enactment of the MDA, Medtronic does not contest that device manufacturers did not conceive the notion that § 360k(a) might preempt damages claims until nearly 15 years later.[5]

Nonetheless, Medtronic argues that the plain language of § 360k(a) compels a finding of preemption. It begins (at 26-27) by stating that *Lohr*'s "holding" is that state-law damages claims constitute requirements under § 360k(a). That statement is incorrect. Although five members of the Court expressed the view that tort duties can constitute "requirements" under § 360k(a), the point was neither part of the Court's holding nor necessary to it. And while Medtronic is correct that *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992), and *Bates*, 544 U.S. at 443, hold that common-law rules can constitute "requirements" within the meaning of the Public Health Cigarette Smoking Act of 1969 ("Cigarette Labeling Act") and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), the Court has also recognized that the word does not "invariably carry this meaning." *Bates*, 544 U.S. at 443; *see also Sprietsma*, 537 U.S. at 63 (statute that preempts "a law . . . imposing a requirement" does not preempt common law).

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[5]Medtronic states that the preemption argument was not made with respect to PMA devices for so many years because the FDA did not approve PMA devices for some time after 1976. In reality, a few devices were deemed to have PMA upon enactment of the MDA. 21 U.S.C. § 360(j)(l); *see, e.g.*, 21 C.F.R. § 886.3600 (intraocular lenses). The FDA otherwise issued its first PMA in April 1979. *See Michael v. Shiley, Inc.*, 46 F.3d 1316, 1320 (3d Cir. 1995). By the mid-1980s, injury caused by that device resulted in "numerous lawsuits." *Bowling*, 143 F.R.D. at 147; *see, e.g., Khan v. Shiley, Inc.*, 266 Cal. Rptr. 106, 108 (Cal. Ct. App. 1990) (complaint filed in 1986). Moreover, prior to *Lohr*, device manufacturers made little distinction between PMA and 510(k) for preemption purposes, yet Medtronic offers no reason for the long delay in making the preemption argument as to 510(k) devices.

Therefore, Medtronic cannot rely on those statutes to demonstrate Congress's intent in enacting § 360k(a) of the MDA.

Medtronic disagrees with Ms. Riegel's reading of § 360k(a), which is based on the rule of construction that a word is presumed to have the same meaning each time that it is used in a single statute or, as here, a single sentence. *See Commissioner v. Lundy*, 516 U.S. 235, 250 (1996). It argues (at 29) that § 360k(a) restricts the federal preemptive requirements to positive enactments through the phrase "applicable under this chapter to the device," but does not restrict preempted state requirements by repeating that phrase. Read in context, however, that argument falls apart. State requirements are limited to those "with respect to a device," just as federal requirements are limited to those "applicable under this chapter to a device." Because state requirements could come from a variety of sources—the statutes and regulations of various states—the exact wording used in regard to the federal requirements could not be applied to the state requirements. Nonetheless, taken as a whole, § 360k(a) evinces Congress's intent that preempted state requirements be "counterparts"—in the word of the relevant FDA regulation, 21 C.F.R. § 808.1(d), and *Lohr*, 518 U.S. at 500—to the federal requirements. Medtronic's reading also ignores the legislative history, which refers to preemption only of state statutes and regulations, and the regulatory commentary accompanying issuance of 21 C.F.R. § 808.1, which often mentions state positive law but never once mentions damages claims. *See* 43 Fed. Reg. 18661. Furthermore, even if Medtronic's reading were plausible, in light of the presumption against preemption, the Court has "a duty to accept the reading that disfavors preemption." *Bates*, 544 U.S. at 449.

Arguing that § 360k(a) should be read in context, Ms. Riegel's opening brief pointed to § 360k(b)—the provision that allows the FDA to exempt state requirements from preemption—in support of the argument that § 360k(a) does not

encompass damages claims. Medtronic responds that not every preempted requirement need be amenable to being exempt from preemption. However, in light of the strong presumption against preemption and Congress's striking silence with respect to preemption of damages claims, Medtronic's reading, while possible, is not the most plausible. Further, Medtronic offers no explanation why Congress would single out patients' only means of seeking compensation for injuries caused by defective devices by not allowing an exemption for damages claims, while allowing the possibility of exemption for other sorts of state laws, including laws that directly regulate devices. In contrast, the United States suggests (at 17) that the FDA may be able to exempt common-law duties that are sufficiently specific, but it offers no example applicable in a product liability case. In addition, like Medtronic, the United States has no answer to the practical impediments to seeking an exemption for a common-law duty, other than to say that not every "requirement" needs to fit within the framework of § 360k(b).

B. Medtronic suggests (at 32) that the Court not pay too much attention to the background and purpose of the MDA, and its brief generally follows its own advice. Instead, Medtronic focuses (at 32) on a single line in Ms. Riegel's opening brief, which states that "[i]n 1976, for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented." Pet. Br. 18. By 1976, Medtronic says, Congress had already preempted damages claims against cigarette companies through the Cigarette Labeling Act. That statute does not contradict Ms. Riegel's point, however, because preemption under the Cigarette Labeling Act applies only to certain failure-to-warn claims, and not to design, fraud, or other claims. *Cipollone*, 505 U.S. at 530-31.[6]

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[6]Medtronic also cites ERISA to show that Congress has sometimes preempted state-law claims, but ERISA provides an alternative

(continued...)

In contrast, below, Medtronic argued that *all* claims against it are preempted. *See* 2d Cir. App. A-3 (answer), A-28, A-34-A-36 (motion for summary judgment and affidavit in support thereof). This broad argument was typical of the preemption arguments made by PMA device manufacturers, who often seek preemption as to every claim alleged. *See, e.g., Horn v. Thoratec Corp.*, 376 F.3d 163, 165 (3d Cir. 2004); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 219 (6th Cir. 2000). Now, Medtronic attempts to minimize the breadth of its position by suggesting (at 33) that the scope of preemption is "exceedingly small" because patients injured by PMA devices may still bring claims for failure to comply with FDA-approved design, manufacturing, and labeling specifications. However, the vast majority of injuries to patients caused by PMA devices are not from manufacturers' failure to market the device according to the specifications in the approved PMA, but from defects or inadequacies in those specifications that have either not been identified or not been addressed in time to prevent injury. *See, e.g., In re Medtronic*, 465 F. Supp. 2d 886; *In re Guidant Corp.*, 2007 WL 1725289 (June 12, 2007); *Horn*, 376 F.3d 163; *Kemp*, 231 F.3d 216; *Bowling*, 143 F.R.D. 141.

Similarly, Medtronic (at 49) tries to avoid the consequences of its position by downplaying the number of PMA devices and the injuries they cause. First, Medtronic ignores Congress's intent, firmly established in the MDA, that the FDA require PMA for *all* class III devices. 21 U.S.C. §§ 360e(b)(1), 360e(i); *see* Pet. Br. 4. Second, Medtronic vastly understates

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[6](...continued)
remedy scheme. *See* 29 U.S.C. § 1132(a)(1)(B). Responding to the same sentence of the opening brief, amicus Chamber of Commerce (at 15) cites FIFRA and the Federal Railroad Safety Act ("FRSA"). As with the Cigarette Labeling Act, FIFRA preempts some labeling claims, but not other claims. *See Bates*, 544 U.S. at 444, 447. FRSA allows the Secretary of Transportation to preempt common-law duties in some circumstances but does not itself preempt any. 45 U.S.C. § 434 (1970), *recodified as amended at* 49 U.S.C. § 20106.

the percentage of class III devices that reach the market through PMA by comparing PMA submissions in 2005 to *all* 510(k) submissions that year, not only those submitted for class III devices and not only those submitted for new products. In fact, after excluding class I and II devices, the FDA's databases show that, in fiscal year 2005, 42.5 percent of class III submissions seeking permission to market new devices were PMA applications. If submissions regarding modifications to existing devices are included, more than 92 percent of class III submissions that year were for PMA devices.[7] Third, PMA devices cause a great number of serious injuries. *See* Pet. Br. 44-46 (citing examples); AARP Br. 20-26, 28-30 (same). The ramifications of barring patients from seeking compensation for these injuries are very significant. The notion that Congress did so without a word of debate is not credible.

CONCLUSION

The decision below should be reversed and the case remanded for a trial on the merits.

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[7]These figures were calculated using the FDA databases available at www.fda.gov/cdrh/pmapage.html#pma (pma.zip) and www.fda.gov/cdrh/510khome.html, 1996-current (PMN96CUR.ZIP), merging them with the FDA device classification database, available at www.fda.gov/cdrh/prdcddes.html, and sorting by date of submission and class of device.

Medtronic also suggests (at 50) that if manufacturers remain liable for injuries caused by PMA devices, they will file 510(k) submissions, rather than PMA applications. There is no evidence to support the notion that manufacturers ever seek PMA when the FDA would allow them to market their products through 510(k).

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